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An investigational new drug treatment program for patients with gemcitabine: results for over 3000 patients with pancreatic carcinoma.

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BACKGROUND: An Investigational New Drug (IND) treatment program allows patients access to a drug that has shown activity against a serious or life-threatening disease prior to full Food and Drug Administration (FDA) review and approval. This treatment IND program, in which patients with locally advanced or metastatic pancreatic carcinoma were treated with gemcitabine, began in 1995. METHODS: Eligibility criteria were < or =1 prior chemotherapy regimen; a Karnofsky performance status (KPS) of > or =50; and adequate bone marrow, liver, and renal function. Gemcitabine was given at a dose of 1000 mg/m2 weekly x 7 followed by a week of rest, then weekly x 3 every 4 weeks thereafter. In this program, disease-related symptom improvement (DRSI) was defined retrospectively as 1) improvement in pain (on a 7-point scale) and/or analgesic class (e.g., morphine improving to codeine) and/or KPS (> or =20 points), or 2) stability of these three parameters with a 7% increase in weight from baseline. RESULTS: A total of 3023 patients enrolled. At baseline, 80% of them had Stage IV disease, and 84% had a baseline KPS > or = 70. The median age was 65 years, and 56% of the patients were male. The cumulative DRSI response rate after the fourth cycle was 18.4%. Of 982 patients with tumor response data, there were 14 with complete response and 104 with partial response, for an overall response rate of 12.0% (95% confidence interval [CI], 10.0-14.0%). For 2380 patients with survival data, the median survival was 4.8 months (95% CI, 4.5-5.1 months) and the 12-month survival was 15%. Gemcitabine was well tolerated; only 4.6% of discontinuations were due to adverse events. CONCLUSIONS: Notable disease-related symptom improvement and survival were seen with gemcitabine in this large, compassionate-use setting, and these findings were in agreement with those of earlier registration trials.

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